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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,398	02/27/2004	Kathleen M. Miller	98-P0151US2	4925

27774 7590 09/13/2007

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EXAMINER	
SWEET, THOMAS	
ART UNIT	PAPER NUMBER
3738	

MAIL DATE	DELIVERY MODE
09/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/789,398	MILLER ET AL.	
	Examiner	Art Unit	
	Thomas J. Sweet	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-94* is/are pending in the application.

4a) Of the above claim(s) *1-72* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *73-94* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *various*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Response to Arguments

Applicant's arguments, filed 04/26/2007, with respect to example double patenting have been fully considered and are persuasive. The double patenting rejections using us patents 6887270 and 6921390 have been withdrawn in response to the terminal disclaimers. Provisional double patenting rejections of applications: U.S.S.N. 11/125,296 (US 2006/0264912); U.S.S.N. U.S.S.N. 11/188,367 (US 2005/0271698) Appear below. Applications U.S.S.N. 10/209,476 (US 2004/0022824); 10/377,131 (US 2003/0224033); U.S.S.N. 11/040,864 (US 2005/0161859); and U.S.S.N. 10/846,706 (US 2005/0255230) do not present provisional Double patenting as currently claimed. The first two (10/209,476 and 10/377,131) do not claim triclosan and the later two (11/040,864 and 10/846,706) are methods, which have been restricted out of the current application.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 73-74, 76-77, 80-82, 84 and 86 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22, 24, 25, 27, 30-33 of copending Application No. 11/125,296. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application claims are rendered obvious by the combination of claims 2, 24, 25, 27, 30-33 which meet all of the claim 73-74, 76-77, 80, 82, 84 limitations. Regarding claim 81, it is well known in the art of ureteral stents to use apertures for drainage. Regarding claim 86, it is well known in the art of ureteral stents to have areas of different of durometer value for flexibility.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 73-74, 76-77 and 84 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 8, 9 and 14 of copending Application No. 11/188,367. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application claims are rendered obvious by the combination of claims 1, 8, 9 and 14 which meet all of the 73-74, 76-77 claim limitations including being tubular (catheter are inherently tubular). Regarding claim 81, it is well known in the art of ureteral stents to use apertures for drainage. Regarding claim 84 is product by process resulting in the same structure claimed in 11/188,367. Regarding claim 86, it is well known in the art of urethral stents to have areas of different of durometer value for flexibility.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 73-74, 76-77, 80 and 82 are rejected under 35 U.S.C. 102(a and e) as being anticipated by Schwarz et al (US 20010022988). Schwarz et al discloses a stent (ureteral [0026]) comprising a polymeric tubular shaft, said polymeric tubular shaft comprising triclosan [0028] and a matrix polymer [0031].

Regarding claims 76-77, matrix polymer is an ethylene vinyl acetate copolymer [0031].

Regarding claims 80, wherein said stent further comprises a lubricious hydrophilic coating on an outside surface of said polymeric tubular shaft [0030].

Regarding claim 82, polymeric tubular shaft further comprises a radio-opacifying agent [0004][0051].

Claims 73-74, 76-77 and 84 are rejected under 35 U.S.C. 102(e) as being anticipated by Pinchunk et al (US 20020107330).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the

inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131. Pinchunk et al discloses a stent ([0015] ureteral [0013]) comprising a polymeric tubular shaft [0185], said polymeric tubular shaft comprising triclosan [0073] and a matrix polymer [0016].

Regarding claims 76-77, matrix polymer is an ethylene vinyl acetate copolymer [0016].

Regarding claim 84, melt- extruding [0194]

Claims 73-74, 76-77, 84, are rejected under 35 U.S.C. 102(e) as being anticipated by Bucay-Couto et al (US 2003/0018306)

The applied reference has a common assignee and inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131. Bucay-Couto et al discloses a stent (cl 8,18) comprising a polymeric tubular shaft, said polymeric tubular shaft comprising triclosan (cl 9) and a matrix polymer (cl 19).

Regarding claim 84, polymeric tubular shaft is a melt- extruded tubular shaft [0014].

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 84 is rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Schwarz et al. Schwarz et al discloses a stent as discussed above. The polymeric tubular shaft is structurally the same as the present invention so if is fully capable of being made by melt- extruding (is a product by process limitation which is structurally no different that the claimed invention)

Claims 75, 78-83, 85-94 are rejected under 35 U.S.C. 103(a) as being obvious over Pinchunk et al.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2). Pinchunk et al discloses a stent as discussed above including loading from 1-70 wt % therapeutic agent [0176]. Pinchunk et al

encompasses the ranges of 5-20 and 5-15 wt% therapeutic material, but does not specifically recite these ranges. It is a matter of mere design choice to vary the range within the range specified which is not patentably distinct from the prior art of Pinchunk et al.

Regarding claims 78-79, as discussed above 1-70 wt % therapeutic agent includes the range of 20-40 wt% of one or more therapeutic agents loading into a block copolymer (such as EVA). It is a matter of mere design choice to vary the range within the range specified (20-40 wt % and therefore 60-80 wt% block copolymer) which is not patentably distinct from the prior art of Pinchunk et al. Further more, this range of EVA encompasses vinyl acetate content between 19 wt% and about 28 wt%.

Regarding claims 80 and 89, Pinchunk et al remains silent as to polymeric tubular shaft comprises a lubricious hydrophilic coating. It is well known in the art of ureteral stents to include a lubricious hydrophilic coating for the purpose facilitating delivery. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a lubricious hydrophilic coating on the ureteral stent of Pinchunk et al in order to facilitating delivery.

Regarding claim 81, Pinchunk et al remains silent as to polymeric tubular shaft comprises a plurality of apertures formed in the walls. It is well known in the art of ureteral stents to include plurality of apertures in the walls of the stent for the purpose of drainage. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include plurality of apertures in the walls of the Pinchunk et al ureteral stent in order to provide drainage.

Regarding claims 82, 83 and 88, Pinchunk et al remains silent as to including a radio-opacifying agent such as bismuth subcarbonate. It is well known in the art of ureteral stents to include bismuth subcarbonate as a radio-opacifying agent for the purpose of visualization under

X-ray. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include bismuth subcarbonate as a radio-opacifying agent in the ureteral stent of the Pinchunk et al in order to visualize under X-ray.

Regarding claims 86 and 94, Pinchunk et al remains silent as to the polymeric tubular shaft comprises end regions of different durometer value. It is well known in the art of ureteral stents to include end regions of different durometer value for the purpose of delivery and retention. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include end regions of different durometer value in the ureteral stent of the Pinchunk et al in order to facilitating delivery and retention.

Regarding claims 85 and 87. (Original) The stent of claim 73, wherein said polymeric tubular shaft has a wall thickness ranging from 0.2 mm to 0.8 mm. Pinchunk et al remains silent as to the tubular shaft has a wall thickness ranging from 0.2 mm to 0.8 mm. It is well known in the art of ureteral stents to use tubular shaft has a wall thickness ranging from 0.2 mm to 0.8 mm for the purpose of providing structural stability. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a wall thickness ranging from 0.2 mm to 0.8 mm in the ureteral stent of the Pinchunk et al in order to providing structural stability.

Regarding claims 91-93, the 5-20 wt % triclosan and EVA ureteral stent as rejected above is structurally identical and therefore would function the same as the claimed stent.

Claims 80, 81 and 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bucay-Couto et al. Bucay-Couto et al discloses a ureteral stent as discussed above. However, Bucay-Couto et al remains silent as to the stent further comprises a lubricious hydrophilic coating on an outside surface of said polymeric tubular shaft. It is well known in the art of

ureteral stent to include a lubricious hydrophilic coating on an outside surface for the purpose of facilitating delivery. It would have been obvious to one of ordinary skill in the art at the time the invention was made to add a lubricious hydrophilic coating on an outside surface of the Bucay-Couto et al ureteral stent in order to facilitate delivery.

Regarding claim 81, Bucay-Couto et al remains silent as to the stent including plurality of apertures formed in the walls. It is well known in the art of ureteral stent to include plurality of apertures formed in the walls for the purpose of facilitating drainage. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include plurality of apertures formed in the walls of the Bucay-Couto et al ureteral stent in order to facilitate drainage.

Regarding claim 86, Bucay-Couto et al remains silent as to the polymeric tubular shaft comprises end regions of different durometer value. It is well known in the art of ureteral stents to include end regions of different durometer value for the purpose of delivery and retention. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include end regions of different durometer value in the ureteral stent of the Pinchunk et al in order to facilitating delivery and retention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J. Sweet whose telephone number is 571-272-4761. The examiner can normally be reached on 5:45am - 4:15pm, Tu-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thomas J Sweet
Examiner AU 3738